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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/834,229	EFENDIC
Examiner	**Art Unit**
Christine Saoud	1647

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 2, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *13-21* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *13-21* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *1.5, 7*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I in Paper No. 9 is acknowledged. The traversal is on the ground(s) that claims 20 and 21 have been amended to specify that the compound is a peptide, and therefore should be included with Group I. Applicant's statements regarding search burden are not germane to the issue at hand. The amendment to claims 20 and 21 has made them generic to the invention of Group I, therefore, they will be rejoined with the claims of Group I. Claims 13-21 are pending and under examination in the instant Office action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 20-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A review of the instant application does not support the claims as they now appear; specifically, there is no support for the recitation "a peptide that exerts insulinotropic activity by interacting with the same receptor or receptors with which GLP-1, GLP-1 analogs, and GLP-1 derivatives interact" (claim 20) or "peptide that enhances insulin sensitivity by interacting with the

same receptor or receptors with which GLP-1, GLP-1 analogs and GLP-1 derivatives interact" (claim 21). Applicant points to basis at page 4, lines 7 through 31 and originally filed claims 11 and 12 (Applicant actually referenced claims 12-13, but this was a typographical error). However, original claims 11 and 12 make no mention of "peptide", but state "compound". There is no basis for the narrower recitation "peptide", and this is a different inventive concept from "compound". The disclosure of the specification at page 4 is directed to GLP-1 molecules, and is not directed to the generic recitation of "peptide". Applicant points to pages 6-13 and asserts that "hundreds of different peptides that interact with the GLP-1 receptor are described". This argument is not persuasive because each of the molecules which are disclosed and/or described are molecules which are related to GLP-1 in that they are GLP-1 molecules, analogs or derivatives. This does not equate to "peptides" in the broad meaning of the term, which encompasses any peptide without any relationship to GLP-1. Therefore, the instant specification does not support the claims as they now appear and the claims are new matter.

Claims 20-21 are also rejected for lack of an adequate written description. The claims are directed to a method of reducing morbidity and mortality after myocardial infarction by administering "a peptide that exerts insulinotropic activity by interacting with the same receptor or receptors with which GLP-1, GLP-1 analogs, and GLP-1 derivatives interact" (claim 20) or "peptide that enhances insulin sensitivity by interacting with the same receptor or receptors with which GLP-1, GLP-1 analogs and GLP-1 derivatives interact" (claim 21). However, the instant specification only provides for peptides which are related to GLP-1 in that the peptides are GLP-1, GLP-1 analogs and/or GLP-1 derivatives. The broader recitation of "peptides" is not

supported in the instant specification as filed because there are no examples of peptides which are not related to GLP-1, and therefore, there is no associated structure with the recitation of "peptides", only a function recited in the claims. Therefore, in so far as the claims are directed to peptide agonists of the GLP-1 receptor which are not GLP-1, GLP-1 analogs, or GLP-1 derivatives, the instant specification lacks an adequate written description.

In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant has possession of and what Applicant is claiming. From the specification, it is clear that Applicant has possession of a method of treatment by administration of GLP-1 related molecules, including GLP-1, GLP-1 analogs and GLP-1 derivatives. The subject matter which is claimed is described above and includes methods of treatment by administration of any peptide which agonizes the GLP-1 receptor. First, a determination of the level of predictability in the art must be made in that whether the level of skill in the art leads to a predictability of structure; and/or whether teachings in the application or prior art lead to a predictability of structure. The claims are to methods of treatment using peptides which agonize the GLP-1 receptor to enhance insulin sensitivity or exert insulinotropic activity. However, because the claim relies merely on the ability to interact with the receptor, the recitation of "peptide" encompasses any protein which would interact and activate the GLP-1 receptor. Essentially, there is no positive recitation of structure in the claim except for the fact that the compound is a protein. First, the claim is not limited to peptides with a specific structure. The specification only describes a peptides which are related to GLP-1 in structure and fails to teach or describe any other peptides which are not related to GLP-

1 and function in the manner required by the claims. Therefore, there is a lack of guidance or teaching regarding structure and function because the only examples of peptides are structurally related to GLP-1, and there is no guidance found in the prior art.

Next in making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, each claimed species and genus must be evaluated to determine whether there is sufficient written description to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed. With this regard, the instant application fails to provide a written description of the species or the genus which are encompassed by the instant claim except for peptides which are related to GLP-1. The specification does not provide a complete structure of those peptides which "exerts insulinotropic activity by interacting with the same receptor or receptors with which GLP-1, GLP-1 analogs, and GLP-1 derivatives interact" or "enhances insulin sensitivity by interacting with the same receptor or receptors with which GLP-1, GLP-1 analogs and GLP-1 derivatives interact", and therefore, fails to provide a complete structure of the peptides encompassed by the claims. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. Additionally, because the claims lack any structure for the peptides which are encompassed by the claims, the claims are unsearchable. The art may recognize peptides which have the properties recited in the claims, and these peptides may already be in use for treatment of MI, but without

some description of the structure encompassed by "peptides", no meaningful search of the prior art can be made. The specification fails to provide a representative number of species for the claimed genus because the specification teaches only the embodiments related to GLP-1 and provides no structural description for the broader claimed genus of "peptides". Therefore, the claims are directed subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is confusing for the recitation of "a pharmaceutical composition comprising a compound selected from the group consisting of GLP-1, GLP-1 analogs, and GLP-1 derivatives, a buffer, and a preservative at a dose effective to normalize blood glucose". This claim could be interpreted a number of ways, including reading the members of the Markush group as (1) GLP-1, (2) GLP-1 analogs, (3) GLP-1 derivatives, (4) a buffer, (5) a preservative at a dose effective to normalize blood glucose. It is reasonable to interpret the intentions of Applicant as being that the pharmaceutical composition will include a buffer and a preservative and a compound selected

from the group consisting of GLP-1, GLP-1 analogs, and GLP-1 derivatives, wherein the compound is at a dose effective to normalize blood glucose, but the claim does not convey this single concept as it is currently drafted.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 13-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,277,819. Although the conflicting claims are not identical, they are not patentably distinct from each other because they

are directed to the same methods of treatment using the same GLP-1 compounds. Claim 13 differs in the recitation of a buffer and a preservative, however, the addition of these agents in pharmaceutical applications is routine in the art, and clearly obvious over a method comprising the administration of the GLP-1 compounds alone without mention of other agents in the composition. Claim 14 differs from the patented claims in the recitation of "within the first 72 hours following myocardial infarction", however, this time frame is common for administration of agents for the treatment of MI in the art (such as for anti-clotting agents used for treating MI). Additionally, this time was disclosed in the issued patent, and therefore, this time frame is clearly obvious. The limitations of claims 15-19 were similarly disclosed and encompassed by the patented claims. Therefore, a patent to the pending claims would result in an unjustified or improper timewise extension of the "right to exclude" granted by a patent.

Conclusion

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Christine J. Saoud, Ph.D., whose telephone number is (703) 305-7519. The Examiner can normally be reached on Monday to Thursday from 8AM to 2PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. §§ 1.6(d) and 1.8). NOTE: If Applicant *does* submit a paper by fax, the

original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternate number. Official papers filed After Final rejection filed by fax should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud